

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE  
 (REV. 7-2005)

ATTORNEY'S DOCKET NUMBER

283071US0PCT

TRANSMITTAL LETTER TO THE UNITED STATES

DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/560030

INTERNATIONAL APPLICATION NO.  
 PCT/JP04/08491

INTERNATIONAL FILING DATE  
 10 JUNE 2004

PRIORITY DATE CLAIMED  
 11 JUNE 2003

TITLE OF INVENTION

DRUG NANO-PARTICLE, METHOD AND APPARATUS FOR PREPARING PHARMACEUTICAL PREPARATION USING THE PARTICLE

APPLICANT(S) FOR DO/EO/US

Sanshiro NAGARE, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A power of attorney and/or change of address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
20. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
22. ☐ Express Mail Label No.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. <b>10/560030</b> (known as 37 CFR 1.5)	INTERNATIONAL APPLICATION NO. <b>PCT/JP04/08491</b>	ATTORNEY'S DOCKET NUMBER <b>283071US0PCT</b>													
23. Other items or information:  <div style="display: flex; justify-content: space-between;"> <div>           Application Data Sheet            Notice of Priority            PCT/IB/304            Drawings (8 Sheets)         </div> <div>           Cited References (4)            PTO-1449            Request for Small Entity Status         </div> </div>															
The following fees have been submitted: 24. <input checked="" type="checkbox"/> Basic national fee ..... \$300		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:50%;">CALCULATIONS</th> <th style="width:50%;">PTO USE</th> </tr> <tr> <td>\$ 300.00</td> <td></td> </tr> </table>	CALCULATIONS	PTO USE	\$ 300.00										
CALCULATIONS	PTO USE														
\$ 300.00															
25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0 All other situations. .... \$200		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 200.00</td> <td></td> </tr> </table>	\$ 200.00												
\$ 200.00															
26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. .... \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. .... \$400 All other situations. .... \$500		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 400.00</td> <td></td> </tr> </table>	\$ 400.00												
\$ 400.00															
<b>TOTAL OF 24, 25 and 26 =</b>		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 900.00</td> <td></td> </tr> </table>	\$ 900.00												
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<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.															
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:20%;">Total Sheets</th> <th style="width:20%;">Extra Sheets</th> <th style="width:40%;">Number of each additional 50 or fraction thereof (round up to a whole)</th> <th style="width:20%;">RATE</th> </tr> <tr> <td>- 100 =</td> <td>0 /50 =</td> <td>0</td> <td>x \$250.00</td> </tr> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE	- 100 =	0 /50 =	0	x \$250.00	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 0.00</td> <td></td> </tr> </table>	\$ 0.00					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE												
- 100 =	0 /50 =	0	x \$250.00												
\$ 0.00															
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 130.00</td> <td></td> </tr> </table>	\$ 130.00												
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<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:20%;">CLAIMS</th> <th style="width:20%;">NUMBER FILED</th> <th style="width:20%;">NUMBER EXTRA</th> <th style="width:20%;">RATE</th> </tr> <tr> <td>Total claims</td> <td>13 - 20 =</td> <td>0</td> <td>x \$50.00</td> </tr> <tr> <td>Independent claims</td> <td>5 - 3 =</td> <td>2</td> <td>x \$200.00</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	13 - 20 =	0	x \$50.00	Independent claims	5 - 3 =	2	x \$200.00	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 400.00</td> <td></td> </tr> </table>	\$ 400.00	
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Total claims	13 - 20 =	0	x \$50.00												
Independent claims	5 - 3 =	2	x \$200.00												
\$ 400.00															
MULTIPLE DEPENDENT CLAIMS (if applicable) <input checked="" type="checkbox"/> + \$360.00		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 360.00</td> <td></td> </tr> </table>	\$ 360.00												
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<b>TOTAL OF ABOVE CALCULATIONS =</b>		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 1,790.00</td> <td></td> </tr> </table>	\$ 1,790.00												
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<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 895.00</td> <td></td> </tr> </table>	\$ 895.00												
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<b>SUBTOTAL =</b>		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 895.00</td> <td></td> </tr> </table>	\$ 895.00												
\$ 895.00															
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 0.00</td> <td></td> </tr> </table>	\$ 0.00												
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<b>TOTAL NATIONAL FEE =</b>		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 895.00</td> <td></td> </tr> </table>	\$ 895.00												
\$ 895.00															
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 0.00</td> <td></td> </tr> </table>	\$ 0.00												
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<b>TOTAL FEES ENCLOSED =</b>		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>\$ 895.00</td> <td></td> </tr> </table>	\$ 895.00												
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer Number: 22850

SIGNATURE

Norman F. Oblon

NAME

24,618

REGISTRATION NUMBER

DATE

Dec. 8 2008

Surinder Sachar  
Registration No. 34,423

DOCKET NO.: 283071US0PCT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Sanshiro NAGARE, et al.

SERIAL NO.: NEW U.S. PCT APPLICATION (based on PCT/JP04/08491)

FILED: HEREWITH

FOR: DRUG NANO-PARTICLE, METHOD AND APPARATUS FOR PREPARING  
PHARMACEUTICAL PREPARATION USING THE PARTICLE


**REQUEST FOR SMALL ENTITY STATUS**

This application qualifies for small entity status.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Date: Dec. 8 2005

  
\_\_\_\_\_  
Norman F. Oblon  
Registration No. 24,618

Customer Number

**22850**

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 05/03)

Surinder Sachar  
Registration No. 34,423